



American Public Health Association

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April 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Performance Standard for *Vibrio Vulnificus*; Request for Comments
Docket No. 98P-0504
64 Fed.Reg. 3300 (January 21, 1999)

Dear Sir/Madam,

The American Public Health Association (APHA) wishes to register its support for the Center for Science in the Public Interest (CSPI) petition to the Food and Drug Administration (FDA) to establish a *Vibrio vulnificus* performance standard for raw molluscan shellfish from waters associated with past *Vibrio vulnificus* infections.

The American Public Health Association (APHA) is the oldest and largest organization of public health professionals in the world, representing more than 50,000 people from over 50 disciplines in public health. Our constitutional purpose is to protect and promote personal and environmental health. The APHA's programs are focused on the review of the scientific bases for public health programs and policies; identification of impending scientific and practice problems and their potential effects on the public and the environment; and advancement of public health practice.

Ensuring food safety is one of the core missions of the public health field. APHA's members include front-line food safety professionals, policy-makers, and the health care professionals who care for those stricken by foodborne illness. Reflecting this interest, APHA has been a steadfast advocate for improvements in the US's food safety

system at all levels. *Vibrio vulnificus* represents an important public health problem warranting performance standards in order to better ensure the safety of shellfish sold in commerce.

Since 1989, the pathogen has killed over 100 people and has sickened many more. Existing numbers for *Vibrio vulnificus*-related deaths and illnesses most likely underestimate the true incidences of death and illness because there is no formal, nationwide, surveillance program for *Vibrio vulnificus*-related disease. Even with observed cases of death and illness likely to be underestimated, the observed death toll was 24 in 1996, and 18 in 1998. This is far too high a toll to pay for a food safety hazard that is preventable.

A significant portion of people in the United States are at risk of death or illness from *Vibrio*-contaminated seafood. *Vibrio*-contaminated seafood is a particularly serious threat for people with preexisting chronic diseases such as diabetes, cirrhosis, cancer, and AIDS. These people are at risk of the primary-septicemia form of *Vibrio* infection that has a 50% fatality rate according to the Centers for Disease Control and Prevention (CDC) and FDA. Considering the many millions of people in the U.S. that suffer from these chronic ailments, a significant portion of our population is at risk of severe *Vibrio* infections.

Performance standards play a vital role in public health programs by assuring that programs target resources to the areas of greatest public health concern and providing accountability to the public that public funds are achieving results. APHA has been steadfast in its assertion that Hazard Analysis and Critical Control Point (HACCP) programs are most effective when utilized in conjunction with performance standards for pathogens of significant public health concern. *Vibrio vulnificus* meets this criteria.

We therefore support the CSPI petition and urge the FDA to move forward in the development of a *Vibrio vulnificus* performance standard.

Sincerely,

A handwritten signature in black ink that reads "Richard A. Levinson". The signature is written in a cursive style with a large, looped initial "R".

Richard A. Levinson, MD, DPA
Associate Executive Director for Programs and Policy



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